## REMARKS

Claims 1-33 are pending.

The Office Action states that the application is one of a series of related applications by the same inventor, and asks Applicant to inform the Examiner as to which application first enables the presently claimed subject matter so as to properly select the priority date.

In response, Applicant submits that the priority application No. 06/880,305, filed on June 30, 1986 and issued as U.S. Patent No. 4,925,789 is the application that first enables the presently claimed invention.

The Office Action states that the Information Disclosure Statement received April 1, 2002 was not considered because the many cited references are not found in this file and are not available to the Examiner. Applicant submits that all except the first three references were submitted in the prior parent applications. However, because the Examiner has indicated that they are not readily accessible to him at this time, Applicant submits herewith copies of references 1-39, 41-45, 47, 48, 50-54 and 56-64 recited in the Information Disclosure Statement filed April 1, 2002. Copies of the remaining four references will be re-submitted as soon as they become available.

Applicant also submits that copies of three new references were submitted with the Information Disclosure Statement filed April 1, 2002, and a copy of a fourth new reference was submitted with a Supplemental Information Disclosure Statement filed on August 14, 2002. Copies of those previously-filed Statements and the new references cited therein are also submitted herewith for the Examiner's convenience. Applicant respectfully requests that the Examiner acknowledge receipt and consideration of these references.

Rejection under 35 U.S.C. §112, First Paragraph:

Claims 1-33 are rejected under 35 U.S.C. §112, first paragraph for lack of enablement. The Office Action states that "the present claims are directed to a method employing a powdered medium lacking a gelling agent." The Office Action recites the following phrases or statements in the specification: "the culture medium, which may be a water solution or a water gel" (page 2,

first full paragraph); "the medium can be present in powder form" (page 9, lines 11-12); and the medium "can be produced in powder form" (page 11, lines 1-2), and then asks "please inform the Examiner as to which specific previous related applications contain related statements." The Office Action states that "nowhere in the specification as originally filed does the culture medium lack a gelling agent" and that "in view that the specification teaches the medium can be a water gel, is not seen as significant because no unexpected results of this feature is described."

First, Applicants submit that the cited statements from the specification regarding powdered medium occur in the priority application No. 06/880,305, filed on June 30, 1986 and issued as U.S. Patent No. 4,925,789. Thus, the limitation is fully enabled and described.

Regarding the question of enablement and/or written description for a medium lacking a gelling agent, in view of the cited statement in the specification "The culture medium, which may be a water solution or a water gel," Applicant submits that the cited statement is characterizing the prior art, not the claimed invention. That the statements are referring to the prior art is clear from the context of the statement, and is specifically stated the paragraph preceding it in the specification. The subject paragraphs are copied below:

> In order to detect microbial pathogens in specimens, whether of human, animal or environmental origin, the *following general procedure is commonly used: the target (and other) microbes in the specimen are,* ***in the prior art,*** inoculated with the specimen into a culture medium in which they are provided with all the nutrients they require for growth. The specimen may be an untreated natural sample, or it may be a sample which has been pre-treated as, for example, by membrane filtration. The culture medium has the nutrients and other selective chemicals such as antimetabolites or antibiotics, which are selectively active against microbes other than the target microbes. The culture medium is a "general medium", even with the selective chemicals, in that it supports the growth of both target microbes and related microbes and thus is only partially specific to the target microbes.
>
> The culture medium, which may be a water solution or a water gel, is sterilized to rid it of any contaminating microbes which may be present in the medium and which could, therefore, interfere with the analysis. The culture medium must be refrigerated and packaged in such a way to avoid contamination after manufacture.
>
> After one or more of the culture media are inoculated with the specimen, the inoculated media are incubated under controlled atmospheric conditions. After incubation, the culture media are examined for growth of any microbes. If such growth is observed, a sample thereof is taken for further analysis, *since the*

> *presence of the target microbe can only be established by isolating it in the pure state, not mixed with other microbes.* Once isolated on subsequent culture media, the target microbes are identified by testing for a variety of physical and chemical characteristics. *If the apparent target microbe growths are not isolated, false negative tests can result.*
>
> *It will be readily appreciated that this most common analytical procedure is time consuming and must be carefully performed to preserve sterility.* (page 1, line 26 to page 2, line 19; emphasis added).

Applicant submits that the specification paragraphs copied above describe the prior art, the claimed invention being described in the subsequent paragraphs. The prior art is described in order to highlight the disadvantages of then-existing methods of detecting the presence of a particular species of microorganism. Pointing out these disadvantages is a means of underscoring the advance over the prior art made by the claimed invention. The paragraph immediately following these statements recites:

> *This invention* detects target microbes in a sample by using an indicator which is the preferred or primary nutrient for the target microbe, but which cannot be substantially metabolized by any other viable microbes which may be present in the sample along with the target microbe. The invention thus uses an active selector of the target microbes, *rather than the passive reactors used by the prior art.* (page 2, lines 20-24).

Because the statement that the culture medium can be a water solution or a water gel is made only in reference to the prior art, Applicant submits that there is no inconsistency with the negative limitation that the claimed medium "lacks a gelling agent." Further, the specification both enables and describes media lacking a gelling agent, for example, when it recites specific embodiments of medium formulations that do not recite a gelling agent. For example, the medium formulation described on page 6, line 3 to page 7, line 13 (reproduced below) does not recite a gelling agent. The specification recites the following exemplary medium formulation:

"First, to prevent competition from microbes other than the broad category of Gram negative bacteria, the antibiotics vancomycin and ansiomycin are added in the percent by weight of 5%. These antibiotics may be present in the range of 1% to 10% by weight.

Second, to select *E. coli* from Gram negative bacteria, the following ingredients are used:

| INGREDIENT | SOURCE | % BY WEIGHT | RANGE % BY WEIGHT |
|---|---|---|---|
| Nitrogen | ammonium sulfate | 37. | 10-50 |
| Amino Acids | histidine | .0697 | 0.02-0.1 |
| | methionine | .1860 | 0.02-0.4 |
| | tryptophan | .2325 | 0.02-0.5 |
| Vitamins | biotin | .000232 | 0.0001-0.00 |
| | pantothenate | .0093 | 0.001-0.03 |
| | folic acid | .000232 | 0.000 1-0.02 |
| | inositol | .0186 | 0.01-0.02 |
| | P-aminobenzoic acid | .046 | 0.01-.1 |
| | pyrodoxine hydrochloride | .093 | 0.05-0.3 |
| | riboflavin | .037 | 0.01-0.06 |
| | thiamine | 0.37 | 01-0.06 |

| INGREDIENT | SOURCE | % BY WEIGHT | RANGE BY WEIGHT |
|---|---|---|---|
| Elements | ferric chloride | .046 | 0.02-0.1 |
| | copper sulfate | .00186 | 0.00 1-0.002 |
| | manganese sulfate | .0037 | 0.002-0.007 |
| | potassium chloride | .00001 | 0.00001 -0.001 |
| | potassium iodide | .0000046 | 0.000001-0.00001 |
| | zinc sulfate | .046 | 0.01-0.08 |
| | boric acid | .460 | 0.01-0.5 |
| | magnesium chloride | .019 | 0.01-0.05 |
| Salts | potassium phosphate monobasic | 9.0 | 1-15 |
| | potassium phosphate dibasic | 23.0 | 2-30 |
| | sodium carbonate | 23.0 | 2-30 |

| | | | |
|---|---|---|---|
| | magnesium sulfate | 4.6 | 1-10 |
| | sodium chloride | .9 | 0.2-5 |
| | calcium chloride | .9 | 0.2-5 |
| | sodium pyruvate | .023 | 0.01-0.1 |
| Nutrient-indicator | | .345 | 0.2-2 |
| Accelerant | | 2.0 | 1.5-2.5" |

(specification at page 6, line 3 to page 7, line 13)

The recited medium formulation lacks a gelling agent, further supporting the use of this limitation in the instant claims. The specification has not only described media lacking a gelling agent, but has also shown how to make such media and how to use such media in the claimed methods. Thus, the specification demonstrates both possession of media lacking a gelling agent and enablement for the claimed methods of using such media. Thus, the specification satisfies both the written description and the enablement aspects of §112, first paragraph. Applicant notes that the media formulation that does not recite a gelling agent is supported in the earliest priority document, Application No. 06/880,305, filed on June 30, 1986. Similarly, that priority document teaches the remaining elements of the claimed methods, including the powdered medium. Thus, the requirements for written description are satisfied by the present specification and by the specification of the application with the earliest priority date. Applicant respectfully requests withdrawal of this §112, first paragraph rejection.

The Office Action states that "The accelerant found in many instances in the specification is essential to the claimed invention but the specification as originally filed does not provide any written description of what the accelerant may be or how it is made." Applicant respectfully disagrees.

Applicant submits that the instant claims do not recite an accelerant, nor is an accelerant essential to the claimed invention. The specification at page 3, lines 14-30 describes the use of an accelerant to "lessen the time duration from the inception of the test to the alteration (or no alteration) of the sample which indicates the presence (or absence) of the target microbes in the sample" (page 3, lines 25-27). This paragraph makes it clear that the claimed methods will function without an accelerant, but may take more time. Thus, while an accelerant can be useful

to shorten the time required to detect a microorganism, it is not essential to the claimed invention. Because an accelerant is neither essential for nor recited in the claims, Applicant respectfully requests the withdrawal of this rejection under §112, first paragraph.

Rejection under 35 U.S.C. §112, Second Paragraph:

Claims 1-22 are rejected under 35 U.S.C. §112, second paragraph because the phrase "nutrient indicators" in claim 1(d) lacks definite antecedent basis. Applicant respectfully disagrees.

Applicant submits that in lines 3-5 of claim 1 (sub-section (a)), the claim recites "providing a powdered medium having *one or more nutrient indicators* and ingredients to support the growth of said target microbe, said *one or more nutrient indicators* being operable to alter a detectable characteristic" (emphasis added). Thus, when in sub-section (d) the claim recites that "said detectable characteristic results from one or more target microbes metabolizing one or more of said nutrient indicators," the "one or more of said nutrient indicators" term finds definite antecedent basis in the "one or more nutrient indicators" recited in sub-section (a). Applicant respectfully requests withdrawal of this §112, second paragraph rejection.

Formal Matters:

The Office Action states that the title of the invention is not aptly descriptive, and requests a new title that is clearly indicative of the invention to which the claims are directed. Applicant has amended the title herein.

The Office Action states that the Abstract of the Disclosure is not directed to the claimed invention. Applicant has amended the Abstract herein to more closely reflect the presently claimed invention.

The amendments add no new matter.

Conclusion:

In view of the above, Applicant submits that all issues raised in the Office Action are addressed herein. Applicant respectfully requests reconsideration of the claims.

Respectfully submitted,

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**Version of Amendments Marked to Show Changes:**

Note: Because some text in the original was underlined, additions are shown herein by double underlining.

- Please replace the title, lines 1-3, with the following replacement title:

[DESCRIPTION

DETECTION OF FIRST GENERATION ENVIRONMENTAL SOURCED MICROBES IN AN ENVIRONMENTALLY –DERIVED SAMPLE]

METHOD OF DETECTING FIRST GENERATION ENVIRONMENTAL-SOURCED MICROBES IN AN ENVIRONMENTALLY-DERIVED SAMPLE

- Please replace the Abstract on page 16 with the following replacement abstract:

[The presence or absence of a predetermined target first generation environmental sourced microbe in an environmentally derived sample is determined by adding a testing medium to the sample, or vice versa. The testing medium provides a selective growth medium for the target microbe and includes a specific nutrient which only the target microbe can metabolize. This specific nutrient is modified by attaching a sample-altering moiety thereto, thereby converting the nutrient to a nutrient-indicator. The sample-altering moiety is activated to alter the sample only if the specific nutrient is metabolized by the target microbe. The sample-altering moiety can be a material which changes the color of the sample (visible or non-visible) or changes an electrical characteristic of the sample, or alters some other detectable characteristic of the sample. The testing media does not have to be kept sterile, and the testing procedure does not have to be performed in a sterile environment. The medium also includes an accelerant which hastens the advancement of the target microbes to the log phase of growth during the testing procedure.]

The invention relates to a method of detecting the presence or absence of a target microbe in a liquid sample, the method comprising: providing a powdered medium having one or more nutrient indicators and ingredients to support the growth of the target microbe, the one or more

nutrient indicators being operable to alter a detectable characteristic in a medium/sample mixture when metabolized by the target microbes so as to confirm the presence or absence of target microbes in the sample, wherein the medium lacks a gelling agent and the medium is free of target microbes before mixing with a sample; providing a liquid sample; combining the powdered medium and the liquid sample to form a medium/sample mixture; and observing the mixture for the presence or absence of a detectable characteristic wherein the presence of the detectable characteristic results from a target microbe metabolizing a nutrient-indicator.